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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/14/2004

Matthew B. Johnson

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

05/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/824,019	Applicant(s) JOHNSON ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/01/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of IDS filed on 07/01/04 is acknowledged.

Restriction/Election

2. Applicant's election with traverse of Group I, claims 1-17 in the reply filed on 02/20/08 is acknowledged. The traversal is on the ground(s) that the classification of groups I and II in different classes is not necessarily sufficient grounds of restriction requirement. This is not found persuasive because the examiner is required to show one way distinctiveness between the groups which the examiner has done so.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/20/08.

Claims **1-17** are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112~ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurkar, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111, (Fed.Cir. 1991), states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (p. 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., a thermoplastic elastomer and olefinic polymer.

Claim 1 recites the thermoplastic polymer and olefinic polymer. The structural characteristics of the claimed polymers are not specified in claims. In the absence of such, the structural and functional characteristics of the claim cannot be deduced. The structural features of outer and inner shell layers are also not defined by the claims thereby lacking the adequate written description requirement showing possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims encompass numerous species that are not further described. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." *Lizardtech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a thermoplastic elastomer and olefinic polymer, one of skill in the art would not

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recognize from the disclosure that the applicant was in possession of the genus.

Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord *Ex Parte Kubin*, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "11 or more". It is unclear if the limitation is only 11 or more than 11, in which case there's no limit which makes the claim indefinite. Claim 9 refers to reservoir 10 and thus is indefinite. Claims 8 and claim 11 recite the functional properties such as moisture vapor transmission rate and oxygen transmission rate and refer back to claim 1. It is respectfully pointed out that such characteristics are

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associated with the structural limitations of the transdermal delivery device. Claim 1 lacks specific outer and inner layer structure, mere recitation of at least one of the shell layers comprising homopolymer of polypropylene does not adequately describe the complete structure of the compounds constituting outer and inner shells of the device. The metes and bounds of the claim is also not defined. Similar is the case with claim 17 which also does not define exact constituents of outer or inner polymer in addition to not defining specific thermoplastic elastomer and olefinic polymer. Examiner suggests reciting specific compounds or representative no. of compounds in order to specifically account for the functional limitations claimed in claims 8, 11 and 17 and also to make the claimed invention distinctly pointing and distinctly claiming the subject matter of invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication (2004/0202708 A1) to Roehrig et al.

Roehrig et al. discloses a transdermal drug delivery device for delivering pharmaceutically active agents comprising reservoir and a substantially continuous

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translucent barrier layer adjacent to at least a portion of the reservoir. (Abstract).

Various pharmaceutically active agents are disclosed on paragraph [0016] It is further stated that the inorganic barrier layer may be separated by other polymeric layers (see paragraph [0019])). The inorganic barrier layer can be of thickness less than 200 nm (see paragraph [0022]. On paragraph [0025] the reference discloses various polymer layers which can be applied by conventional coating methods. The thickness of polymer layers is more than 10 nm preferably more than 100 nm (paragraph [0027]). Surface area is depicted on paragraph [0029]. The typical polymers constituting the backing film could be polypropylene {paragraph 30}. The reference discloses the measurement of moisture and oxygen transmission (see paragraph [0040 and 0041]. Based on the teachings of the prior art , it would have been obvious to one of ordinary skilled in the art at the time of the instant invention to prepare a transdermal device comprising a reservoir and multiple polymeric layers with a reasonable expectation of success. regarding the thickness of the layers , it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time of the instant invention by doing experimental manipulations in order to get the desired moisture and oxygen transmission rate with a reasonable expectation of success absent evidence to the contrary. Regarding functional characteristics, oxygen and moisture transmissions, it is the position of the examiner that since the polymers disclosed in the prior art is same as claimed; one would expect the device to exhibit similar properties. Furthermore, such properties can be optimized by varying the polymeric layer

concentration. The invention was thus obvious to one of ordinary skilled in the art at time of the instant invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612